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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,555	09/25/2000	Veronique M. Braud	SHP-PT059	9366

3624 7590 10/11/2005

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EXAMINER	
VANDERVEGT, FRANCOIS P	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,555	BRAUD ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2005 and 26 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-34,36,37,42-47 and 49-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *32-34,36,37,46 and 51-53* is/are allowed.

6)☒ Claim(s) *42-45,47,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a rule 371 continuation of PCT Serial Number PCT/GB98/03686.

Claims 1-31, 35, 38-41 and 48 have been canceled.

New claims 50-53 have been added.

Claims 32-34, 36, 37, 42-47 and 49-53 are currently pending

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 26, 2005 has been entered.

Election/Restrictions

2. In view of Applicant's remarks filed May 26, 2005 and the request for continued examination filed August 26, 2005, the **restriction requirement have been withdrawn**.

Accordingly, claims 32-34, 36, 37, 42-47 and 49-53 are the subject of examination in the present Office Action.

3. **In view of Applicant's amendment and remarks filed May 26, 2005, no outstanding grounds of rejection are maintained**.

The following represent new grounds of rejection.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 42-45, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 42-45 are dependent claims drawn to compounds "identified by the method according to claim 32...as used in medical diagnostic procedures." Claims 47 and 49 are dependent claims each reciting a method "using the identified compounds in medical diagnostic procedures." These are reach-through claims and lack adequate written descriptive support of the claimed compounds and their use in the claimed procedures.

Base claims 32 and 46 each recite a method for identifying compounds that affect HLA-E binding to CD94, but the specification does not disclose the compounds identified by the method. The claimed method of medical diagnostic procedures thus cannot be practiced based upon the instant specification, even considering the knowledge of one skilled in the art. No compounds that will perform the claimed medical diagnostic procedures are disclosed, nor has any evidence been shown that such a compound was known. The specification describes assays for screening compounds and even what can be done with any compounds that may potentially be identified through those assays, including medical diagnostic procedures. However, the specification does not disclose just which compounds have the desired characteristic of affecting HLA-E binding to CD94. without such disclosure, the claimed method cannot be said to have been described. (See Univ. Rochester v... (CAFC, 2004) 69USPQ2d 1886)

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111) clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, ((CAFC, 1991) 18 USPQ2d 1016).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step for producing any compound. The claim is drawn to a method of producing a compound that affects the binding of HLA-E to CD94/NKG2 receptors. However, the claim recites only steps for selecting a test compound, incubating the test compound with cells and determining whether the compound affects binding. There is no provision for a step to "produce" the compound.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 42-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Mingari et al. (Int. Immunol. [1995] 7(4):697-703; U on form PTO-892).

Mingari teaches that NK cells express surface receptors for defined groups of HLA class I alleles and that interaction of these receptors and HLA class I molecules inhibits NK-mediated target cell lysis of the HLA class I-bearing cell. Mangari teaches CD94 as an NK-related functional receptor for HLA class I (Abstract in particular).

Mingari teaches anti-CD94 monoclonal antibodies that inhibit the CD94+ cell's ability to lyse HLA class I positive target cells (Abstract, pages 699-701 and Figures 4-6 in particular). While Mingari exemplifies that the antibodies interfere with interaction of CD94 and HLA-C, the antibodies may also interfere with CD94 interaction with HLA-E. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Mingari further teaches that treating the target cells with anti-HLA class I antibodies A6-136 or 6A4 'restores' the ability of NK cells to lyse HLA class I positive target cells (page 699, first column,

Table 1 and Figure 1 in particular). While Mingari does not specifically teach that the monoclonal antibodies A6-136 and 6A4 bind HLA-E, silence about a particular property does not necessitate its absence. Mingari does not teach whether the mAbs specifically bind to HLA-C or whether the bind HLA class I molecules more broadly. Given that the antibodies taught by Mingari alters the interaction between NK cells and HLA class I positive cells, the antibodies may bind HLA-E and inhibit its interaction with CD94/NKG2 receptors. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

The recitation in the claims that the claimed antibodies are identified by the methods recited in other claims merely constitutes the recitation of a "product-by-process" manner of identifying the antibodies. If an antibody is identified by another in a different manner but would also be functional in the claimed identification method, the antibody is the same. The patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claim (see, for example, *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985)). Absent a showing that there is a physical difference between the antibodies taught by Mingari and the instantly claimed antibodies, the products are seen as being the same. The prior art teaching anticipates the claimed invention.

Conclusion

8. Claims 32-34, 36, 37, 46 and 51-53 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:0 and; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D.
Patent Examiner
October 3, 2005

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182